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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,215	01/03/2007	Kazuo Suzuki	2006_1634A	7223
513 7590 08/12/2011 WENDEROTH, LIND & PONACK, L.L.P. 1030 15th Street, N.W., Suite 400 East Washington, DC 20005-1503				
EXAMINER DICKINSON, PAUL W				
ART UNIT 1618		PAPER NUMBER		
NOTIFICATION DATE 08/12/2011		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com  
coa@wenderoth.com

# Office Action Summary

**Application No.**

10/594,215

**Applicant(s)**

SUZUKI ET AL.

**Examiner**

PAUL DICKINSON

**Art Unit**

1618

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 June 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 5-7, 15-18, 21, 22 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-7, 15-18, 21-22, 24-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ ~~Copies of the certified copies of the priority documents have been received in this National Stage~~  
application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 6/8/2011.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Species B renal dysfunction in the reply filed on 6/6/2011 is acknowledged.

Upon further consideration, the Examiner withdrawals the election of species requirement. The election of species requirement is withdrawn and all species (hyperinsulinism, renal dysfunction, and fatty liver) are under consideration.

### ***Response to Arguments***

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The rejection of claims 1-3 and 5-7 under 35 U.S.C. 102(b) as being anticipated by WO 2003011308 (WO '308) is maintained.

The rejection of claims 1-3 and 6-7 under 35 U.S.C. 102(b) as being anticipated by Garg (Ann. Inter. Med., 1994) is maintained.

Applicant argues that WO '308 and Garg fail to teach improving insulin resistance, but rather, teach inhibition of blood sugar elevation in type 2 diabetes patients. A compound having decreasing action on the blood glucose level does not necessarily improve action on insulin resistance. Therefore WO '308 and Garg cannot anticipate or render obvious the claims, as they fail to teach improving insulin resistance.

Applicant's arguments have been fully considered but are not found persuasive. "Improving insulin resistance" is a broad term. Insulin resistance is a physiological condition where the natural hormone insulin becomes less effective at lowering blood sugars. Type 2 diabetes results from insulin resistance (see instant specification, paragraph 36). The reason blood glucose levels in diabetes patients elevates outside the normal range is because of insulin resistance. Thus inhibiting blood sugar elevation in type 2 diabetes patients (which WO '308 and Garg teach their agents do) is improving insulin resistance, as it is mitigating the effect of insulin resistance, that is, it is inhibiting elevation of blood glucose levels which would otherwise elevate because of insulin resistance in these patients. As the method of WO '308 and Garg inhibit elevation of blood glucose levels which would otherwise increase because of insulin resistance in these patients, it is a method of improving insulin resistance. Furthermore, the references meet every limitation of the claimed method in that the prior art method comprises administering orally to a diabetes patients (a patient in need of improving insulin resistance) colestimide as an active ingredient (an insulin resistance-improving

agent comprising a pharmaceutically acceptable anion exchange resin as an active ingredient).

The rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by JP 2002-537390 (JP '390) is maintained.

Applicant argues that JP '390 fails to teach or suggest that an anion exchange resin is effective for improvement of insulin resistance, but rather, teaches that cholestyramine and colestipol are taught for treatment of hypolipidemia/hypolipoproteinemia.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner agrees that cholestyramine and colestipol are taught for treatment of hypolipidemia/hypolipoproteinemia. However, as stated previously, JP '390 teaches that a compound of its Formula (I) can be used to treat insulin resistance either by itself or in combination with the hypolipemia/hypolipoproteinemia drugs cholestyramine and colestipol. The above method, where cholestyramine and/or colestipol are added in combination with a compound of Formula (I) to treat insulin resistance, is a method for improving insulin resistance. It is a method for improving insulin resistance which comprises administering orally to a patient in need thereof a composition comprising a compound of Formula (I) and cholestyramine and/or colestipol.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-16, 21-22, 25-28, 31-32, and 34-35 are rejected under 35

U.S.C. 102(b) as being anticipated by US 5468727 ('727). '727 teaches a method for the treatment of hyperinsulinemia (hyperinsulinism; a disease or symptom resulting from insulin resistance) comprising orally administering cholestyramine resin (a pharmaceutically acceptable anion exchange resin having bile acid adsorbing ability) as an active agent to a patient in need thereof (abstract; claims 1-2 and 7; Example 3). An oral hypoglycemic agent, such as chlorpropamide (a sulfonylurea agent), may be administered simultaneously (col 5, lines 10-13; col 4, lines 57-60).

Claims 15, 17, 21-22, 24, 27, 29, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0793960 (EP '960). EP '960 teaches a method for the treatment of renal dysfunction (a disease or symptom resulting from insulin resistance)

comprising orally administering colestimide or cholestyramine resin (pharmaceutically acceptable anion exchange resins having bile acid adsorbing ability) as an active ingredient to a patient in need thereof (abstract; page 4, lines 54-55; page 5, lines 13-14 and 23-27; claims 1-3 and 7-8).

Claims 15, 18, 21-22, 27, and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 9841216 (WO '216). WO '216 teaches a method for the treatment of fatty liver (a disease or symptom resulting from insulin resistance) comprising orally administering cholestyramine resin (pharmaceutically acceptable anion exchange resin having bile acid adsorbing ability) as an active ingredient to a patient in need thereof (abstract; page 3, lines 1-10; page 4, lines 2-17).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul W. Dickinson whose telephone number is 571-270-3499. The examiner can normally be reached on Mon-Thur 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 217-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul W. Dickinson

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Examiner  
Art Unit 1618

August 5, 2011

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618